

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

---

Claim 1 (currently amended): A method for non-invasively determining a condition of the circulatory system of a subject, the subject inhaling and exhaling breathing gases during breathing, said method comprising the steps of:

5 (a) measuring the amount of CO<sub>2</sub> in the breathing gases exhaled by the subject and the CO<sub>2</sub> concentration of the breathing gases exhaled by the subject for a first (1) breathing condition of the subject;

(b) determining at least one value of the amount of CO<sub>2</sub> released from the circulatory system of the subject (VCO<sub>2</sub><sup>1</sup>) using the amount of CO<sub>2</sub> in the breathing gases exhaled when the subject is in the first condition;

B | 10 (c) determining at least one value for a quantity indicative of the end capillary blood CO<sub>2</sub> content of the subject using the CO<sub>2</sub> concentration of the breathing gases exhaled when the subject in the first condition;

(d) altering the CO<sub>2</sub> concentration in the lungs of the subject;

15 (e) measuring the amount of CO<sub>2</sub> in the breathing gases exhaled by the subject and the CO<sub>2</sub> concentration of the breathing gases exhaled by the subject for at least one breath of the subject under second (2) breathing conditions of altered CO<sub>2</sub> in the lungs of the subject;

20 (f) determining at least one value for the amount of CO<sub>2</sub> released from the circulatory system of the subject (VCO<sub>2</sub><sup>2</sup>), the determination of the value being carried out in a time period less than that required for blood leaving the lungs of the subject to pass through the circulatory system of the subject and return to the lungs, the determination of the value using the amount of CO<sub>2</sub> in the exhaled breathing gases for the second breathing condition;

25 (g) determining at least one value for a quantity indicative of the end capillary blood CO<sub>2</sub> content of the subject, the determination of the value being carried out

in a time period less than that required for blood leaving the lungs of the subject to pass through the circulatory system of the subject and return to the lungs, the determination of the value using the CO<sub>2</sub> concentration of the breathing gases exhaled for the second breathing condition; and

30 (h) performing a regression analysis using the determined VCO<sub>2</sub><sup>1</sup>, VO<sub>2</sub><sup>2</sup>, and end capillary blood CO<sub>2</sub> quantity values to establish a regression line; ~~and~~

(i) extrapolating the regression line to obtain a value for the end capillary blood CO<sub>2</sub> quantity when the amount of CO<sub>2</sub> released from the circulatory system of the subject (VCO<sub>2</sub>) is zero; and

35 determining a further value for the quantity indicative of the end capillary blood CO<sub>2</sub> content for breathing of the subject in the first breathing condition;

forming a relationship between the value for the quantity indicative of the end capillary blood CO<sub>2</sub> content for breathing in the first breathing condition used in the regression analysis and the value obtained by extrapolating the regression line in step (i);

40 and

applying the relationship to the further determined value for a quantity indicative of the end capillary blood CO<sub>2</sub> content to provide a new value for the value which was obtained by the extrapolation of the regression line in step (i).

Claim 2 (original): The method according to claim 1 wherein steps (a) and (e) are further defined as measuring end tidal CO<sub>2</sub> concentrations of the breathing gases exhaled by the subject.

Claim 3 (original): The method according to claim 2 further defined in that the quantity, for which values are determined in steps (c) and (g), comprises the end tidal CO<sub>2</sub> concentration of the exhaled breathing gases and that the value obtained in step (i) is the end tidal CO<sub>2</sub> concentration when the amount of CO<sub>2</sub> released from the circulatory system of the subject  
5 (VCO<sub>2</sub>) is zero.

Claim 4 (original): The method according to claim 1 further defined in that the quantity, for which the values are determined in steps (c) and (g), comprises the CO<sub>2</sub> partial pressure in the blood of the subject and that the value obtained in step (i) is the CO<sub>2</sub> partial pressure of the end capillary blood of the subject when the amount of CO<sub>2</sub> released from the circulatory system of the subject (VCO<sub>2</sub>) is zero.

B | 5 Claim 5 (original): The method according to claim 1 or 2 further defined in that the quantity, for which the values are determined in steps (c) and (g), comprises the CO<sub>2</sub> content of the end capillary blood (CcCO<sub>2</sub>) of the subject and that the value obtained in step (i) is the CO<sub>2</sub> content of the end capillary blood of the subject when the amount of CO<sub>2</sub> released from the circulatory system of the subject (VCO<sub>2</sub>) is zero, which value comprises the CO<sub>2</sub> content of venous blood (CvCO<sub>2</sub>).

Claim 6 (previously amended): The method according to claim 1 further including the step of using the value obtained in step (i) to determine the functional cardiac output (FCO) of the subject using a non-differential form of the Fick equation.

Claim 7 (previously amended): The method according to claim 1 further defined as including the steps of:

5 determining further values for the amount of CO<sub>2</sub> released from the circulatory system of the subject (VCO<sub>2</sub>) and for the quantity indicative of the end capillary blood CO<sub>2</sub> content for breathing of the subject in the first breathing condition; and  
using the value provided by the extrapolation of the regression line in step (i) and a further determined released CO<sub>2</sub> amount (VCO<sub>2</sub>) and value for the quantity indicative of end capillary blood CO<sub>2</sub> content to determine the functional cardiac output of the subject using a non-differential form of the Fick equation.

Claim 8 (original): The method according to claim 7 further defined as being carried out on a breath-by-breath basis.

Claim 9 (canceled)

Claim 10 (currently amended): The method according to claim 1 ~~9~~ further defined as forming a relationship comprising as a ratio.

Claim 11 (currently amended): The method according to claim 1 ~~9~~ further defined as forming a relationship comprising a difference.

31  
Claim 12 (currently amended): The method according to claim 1 ~~9~~ further including the steps of:

determining further values for the amount of CO<sub>2</sub> released from the circulatory system of the subject (VCO<sub>2</sub><sup>N</sup>) for breathing of the subject in the first breathing  
5 condition; and

using the further determined released CO<sub>2</sub> amount (VCO<sub>2</sub><sup>1</sup>), the further determined value for a quantity indicative of the end capillary blood CO<sub>2</sub> content, and the new value for the value which was obtained by extrapolation of the regression line in a non-differential form of the Fick equation to determine the functional cardiac output (FCO) of  
10 the subject.

Claim 13 (currently amended): The method according to claim 1 ~~9~~ further defined as being carried out on a breath-by-breath basis.

Claim 14 (original): The method according to claim 1 wherein the step of altering the CO<sub>2</sub> concentration in the lungs of the subject is further defined as increasing the CO<sub>2</sub>

concentration in the lungs of the subject to reduce CO<sub>2</sub> gas exchange in the lungs of the subject.

Claim 15 (original): The method according to claim 14 wherein the step of increasing the CO<sub>2</sub> concentration in the lungs of the subject is further defined as increasing the CO<sub>2</sub> content of the breathing gases inhaled by the subject.

Claim 16 (original): The method according to claim 15 further defined as administering a bolus of CO<sub>2</sub> into the breathing gas inhaled by the subject.

β | Claim 17 (original): The method according to claim 15 further defined as causing the subject to inhale breathing gas previously exhaled by the subject.

Claim 18 (original): The method according to claim 15 wherein step (d) is further defined as increasing the CO<sub>2</sub> by an amount which improves the accuracy of the determination while avoiding undue build up of CO<sub>2</sub> in the blood of the subject.

Claim 19 (original): The method according to claim 1 wherein the step of altering the CO<sub>2</sub> concentration in the lungs of the subject is further defined as decreasing the CO<sub>2</sub> concentration in the lungs of the subject to increase CO<sub>2</sub> gas exchange in the lungs of the subject.

( Claim 20 (original): The method according to claim 19 wherein the step of decreasing the CO<sub>2</sub> concentration in the lungs of the subject is further defined as increasing the ventilation of the subject.

Claim 21 (original): The method according to claim 5 further defined as including the steps of:

determining the amount of oxygen in the venous blood of the subject; and  
altering the obtained value for the venous blood CO<sub>2</sub> content (CvCO<sub>2</sub>) in  
5 accordance with the amount of oxygen in the blood to provide a CO<sub>2</sub> partial pressure value  
(PvCO<sub>2</sub>) for venous blood.

Claim 22 (original): The method according to claim 21 wherein the step of the determining  
the amount of oxygen in the venous blood is further defined as determining the degree of  
oxygen saturation of the venous blood.

Claim 23 (original): The method according to claim 21 further defined as including the  
steps of:

determining a further value for the quantity indicative of the end capillary  
blood CO<sub>2</sub> content for breathing of the subject in the first breathing condition;

B<sub>1</sub> 5 forming a relationship between the value for the quantity indicative of the end  
capillary blood CO<sub>2</sub> content for breathing in the first breathing condition used in the  
regression analysis and the CvCO<sub>2</sub> value obtained by extrapolating the regression line in  
step (i);

10 applying the relationship to the further determined value for a quantity  
indicative of the end capillary blood CO<sub>2</sub> content to provide a new CvCO<sub>2</sub> value; and

altering the new CvCO<sub>2</sub> value in accordance with the amount of oxygen in the  
blood to provide a new CO<sub>2</sub> partial pressure value (PvCO<sub>2</sub>) for venous blood.

Claim 24 (original): The method according to claim 23 further defined as forming a  
relationship comprising a ratio.

Claim 25 (original): The method according to claim 23 further defined as forming a  
relationship comprising a difference.

Claim 26 (previously amended): The method according to claim 21 further defined as carrying out the method on a breath-by-breath basis.

Claim 27 (currently amended): The method according to claim 1 further defined as performing linear regression analysis using the  $VCO_2^1$ ,  $VO_2^2$ , and ~~1 and 2~~ values for the quantity indicative of the end capillary blood  $CO_2$  content of the subject determined using the exhaled breathing gas  $CO_2$  concentrations for the first and second conditions.

Claim 28 (original): The method according to claim 1 where the breathing gases supplied to the subject comprise air.

B | Claim 29 (original): The method according to claim 1 further including the step of allowing the subject to take a sufficient number of breaths to stabilize the  $CO_2$  content and  $CO_2$  concentration of the exhaled breathing gases before taking the breathing measurements for the first breathing condition of the subject.

Claim 30 (original): The method according to claim 1 further defined as determining a plurality of values for at least one of the amount of  $CO_2$  removed from the lungs of the patient ( $VCO_2$ ) and the quantity indicative of the end capillary blood  $CO_2$  content for use in performing the regression analysis.

Claim 31 (original): The method according to claim 1 wherein steps (b) and (f) are further defined as determining at least one value of the amount of  $CO_2$  released from the circulatory system of the subject ( $VCO_2$ ) using the  $CO_2$  content of the inhaled and exhaled breathing gases.

Claim 32 (original): A method for determining a change in a measured condition of the circulatory system of a subject, said method comprising the steps of:

(a) non-invasively obtaining an initial value for at least one selected variable capable of indicating changes in a measured circulatory system condition of the  
5 subject;

(b) carrying out a discrete measurement of a circulatory system condition of a subject;

(c) obtaining a further value for the at least one selected variable subsequent to carrying out the discrete measurement

10 (d) comparing the subsequent value of the variable with the initial value of said variable to determine whether the obtained variable has changed in value.

β1 Claim 33 (original): The method according to claim 32 wherein the selected variable comprises at least one of exhaled CO<sub>2</sub> amount, end tidal CO<sub>2</sub> amount, heart rate, and the amount of CO<sub>2</sub> released from the blood of the subject (VCO<sub>2</sub>).

Claim 34 (original): The method according to claim 32 further defined as compensating the values of the selected indicator variable for changes in the condition of the subject not arising from circulatory system conditions.

Claim 35 (original): The method according to claim 34 further defined as compensating a selected indicator variable for changes in ventilation of the subject.

Claim 36 (original): The method according to claim 32 wherein the discrete measurement of circulatory system condition in step (b) is carried out using Fick Equation 1 and the quantities expressed therein and the circulatory system condition is the functional cardiac output (FCO).



Claim 37 (original): The method according to claim 32 wherein the discrete measurement of circulatory system condition in step (b) is carried out using Fick Equation 2 and the quantities expressed therein.

Claim 38 (original): The method according to claim 37 wherein the at least one selected variable further comprises at least one of the amount of CO<sub>2</sub> released from the blood of the subject (VCO<sub>2</sub>) and the end tidal CO<sub>2</sub> amount for normal conditions of the subject.

Claim 39 (original): The method according to claim 37 wherein the measured circulatory system condition is functional cardiac output (FCO).

31 Claim 40 (original): The method according to claim 32 wherein the discrete measurement of circulatory system condition is carried out using the quantities expressed in Fick Equation 2 and the circulatory system condition is venous blood partial CO<sub>2</sub> pressure (PvCO<sub>2</sub>).

Claim 41 (original): The method according to claim 39 wherein the at least one selected variable further comprises at least one of the amount of CO<sub>2</sub> released from the blood (VCO<sub>2</sub>) and end tidal CO<sub>2</sub> for normal conditions of the subject.

Claim 42 (original): The method according to claim 32 wherein the discrete measurement of the circulatory system condition in step (b) is carried out using a blood dilution technique.

Claim 43 (original): The method according to claim 42 wherein the blood dilution technique uses a marker dye.

Claim 44 (original): The method according to claim 42 wherein the blood dilution technique uses thermodilution.

Claim 45 (original): The method according to claim 42 wherein the circulatory system condition measured is cardiac output (CO).

Claim 46 (original): The method according to claim 32 wherein step (c) is further defined as sequentially obtaining further values of the at least one selected variable for comparison with the initial value.

Claim 47 (original): The method according to claim 46 further defined as obtaining further values on a breath-by-breath basis.

Claim 48 (original): The method according to claim 46 further defined as obtaining further values on a heart beat by heart beat basis.

B1  
Claim 49 (original): The method according to claim 32 further defined as allowing disturbances caused by the carrying out of the discrete measurement to subside before obtaining a further value for said at least one selected variable.

Claim 50 (original): The method according to claim 37 further defined as allowing disturbances caused by the carrying out of the discrete measurement to subside before obtaining a further value for said at least one selected variable.

Claim 51 (original): The method according to claim 32 wherein step (d) is further defined as determining whether the variable has changed by a predetermined amount.

Claim 52 (original): The method according to claim 32 further defined as initiating an action responsive to a change in the variable.

Claim 53 (original): The method according to claim 52 further defined as initiating a further carrying out of a discrete measurement of a circulatory system condition of the subject.

Claim 54 (original): The method according to claim 52 further defined as providing an indication that a change in the value of the variable has occurred.

Claim 55 (original): The method according to claim 52 further defined as providing an indication of the amount by which the value of the variable has changed.

Claim 56 (original): The method according to claim 52 further defined as providing an indication of the direction in which a change in the value of the variable has occurred.

B1 Claim 57 (original): The method according to claim 52 further defined as providing an alarm.

Claim 58 (original): Apparatus for determining a change in a measured condition of the circulatory system of a subject, said apparatus comprising:

(a) means for non-invasively obtaining initial and subsequent values for at least one selected variable capable of indicating changes in a measured circulatory system condition of the subject;

(b) means for carrying out a discrete measurement of a circulatory system condition of a subject; and

(c) means for comparing a subsequent value of the variable with the initial value of said variable to determine whether the obtained variable has changed in value.

Claim 59 (original): The apparatus according to claim 58 wherein the selected variable comprises at least one of exhaled CO<sub>2</sub> amount, end tidal CO<sub>2</sub> amount, heart rate, and the amount of CO<sub>2</sub> released from the blood of the subject (VCO<sub>2</sub>).

Claim 60 (original): The apparatus according to claim 58 further defined as including means for compensating the values of the selected indicator variable for changes in the condition of the subject not arising from circulatory system conditions.

Claim 61 (original): The apparatus according to claim 58 wherein the measured circulatory system condition is functional cardiac output (FCO).

Claim 62 (original): The apparatus according to claim 58 wherein the measured circulatory system condition is venous blood partial CO<sub>2</sub> pressure (PvCO<sub>2</sub>).

B1. Claim 63 (original): The apparatus according to claim 58 wherein the measured circulatory system condition is cardiac output.

Claim 64 (original): The apparatus according to claim 58 wherein the circulatory system condition is measured non-invasively.

Claim 65 (original): The apparatus according to claim 58 wherein the circulatory system condition is measured invasively.

Claim 66 (original): The apparatus according to claim 58 further defined as means for initiating an action responsive to a change in the variable.

Claim 67 (previously added): The method according to claim 3 further including the step of using the value obtained in step (i) to determine the functional cardiac output (FCO) of the subject using a non-differential form of the Fick equation.

Claim 68 (previously added): The method according to claim 4 further including the step of using the value obtained in step (i) to determine the functional cardiac output (FCO) of the subject using a non-differential form of the Fick equation.

B1

Claim 69 (previously added): The method according to claim 5 further including the step of using the value obtained in step (i) to determine the functional cardiac output (FCO) of the subject using a non-differential form of the Fick equation.

---